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Draft Guidance on Zaleplon

October 2024

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Active Ingredient: Zaleplon

Dosage Form: Tablet

Route: Oral

Strengths: 5 mg, 10 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 10 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Subjects should be advised not to drive if they are experiencing drowsiness and/or dizziness at the end of the study.

Analyte to measure: Zaleplon in plasma

Bioequivalence based on (90% CI): Zaleplon

Waiver request of in vivo testing: 5 mg strength based on (i) acceptable bioequivalence study on the 10 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each of both strengths of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended May 2007; Finalized May 2008; Revised October 2024

Unique Agency Identifier: PSG_020859

[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*